UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO	)	Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES INC.'S RULE 56.1 STATEMENT OF ADDITIONAL FACTS THAT PRECLUDE SUMMARY JUDGMENT IN FAVOR OF THE GOVERNMENT

Dated: August 28, 2009

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Defendant Abbott Laboratories Inc., pursuant to Local Rule 56.1 and in support of its *Opposition To The Government's Motion For Partial Summary Judgment*, respectfully submits the following additional, material facts that preclude summary judgment in the Government's favor.[1]

I. BACKGROUND

A. Abbott's Former Hospital Products Division And The Subject Drugs.

1. The Subject Drugs at issue in this matter are Vancomycin (an antibiotic), dextrose, saline, and sterile water (three solutions used in a variety of IV treatments). (6/4/07 United States' First Am. Complaint ¶ 30, Ex. 95.)

2. These multi-source generic products are generally administered via an infusion pump or IV injection. (Montanez Expert Rep. at 4, Ex. 92.)

3. Administration of the Subject Drugs requires much more labor than traditional pharmacy pill dispensing: the products generally must be mixed in a sterile environment per physician's orders, must often be refrigerated and transported directly to a patient's home, and are dispensed through the use of ancillary supplies (such as bags, tubes, and pumps), often with a nurse's assistance. (Montanez Expert Rep. at 11-20, Ex. 92.)

4. Throughout the claims period of 1991-2001, the Subject Drugs were sold by Abbott's former Hospital Product Division ("HPD"). (12/20/05 Sellers Dep. 33:1-8, Ex. 71.)

5. HPD was divided into two business units: the Hospital Business Sector ("HBS") and the Alternate Site Business Sector ("Alternate Site"). (2/13/07 Sellers Dep. 18:22-24, Ex. 72.)

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[1] Evidentiary materials cited in this document are provided as attachments to the August 28, 2009 Declaration of Brian J. Murray, filed herewith, and are cited as (Ex. ___.).

6. HBS and Alternate Site each had their own contracting department, sales force, and administrative staff. (2/13/07 Sellers Dep. 12:5-10; 22:8-23; 24:12-23; 25:2-26:8, Ex. 72.)

7. HBS marketed its products to hospitals, and it accounted for approximately 90% of all HPD revenues. (3/31/08 Sellers Dep. 482:9-15, Ex. 76; 6/3/08 Gonzalez Dep. 88:3-10, Ex. 28.)

8. HBS's hospital customers were not generally reimbursed by reference to compendia prices such as AWP, but rather by Diagnosis Related Group codes – a lump payment that includes all products associated with a particular treatment. (3/16/08 Sellers Dep. 98:2-6, Ex. 75.)

9. Alternate Site serviced medical providers in non-hospital settings, such as clinics and dialysis centers. (5/3/07 Balzer Dep. 35:11-36:3, Ex. 7.)

10. Alternate Site was divided into three business groups: Renal, Alternate Site Product Sales, and Home Infusion Services. (2/13/07 Sellers Dep. 48:6-16, Ex. 72.)

11. The Renal group was responsible for about 50% of Alternate Site revenues. (*See e.g.*, ABT-DOJ 0312188, 0312219, 0312248, 0312279, 0312306, 0312399, 0312583, and 0312708, Ex. 124.)

12. As with HBS's hospital customers, the Renal group's customers were generally not reimbursed by reference to compendia prices, such as AWP. Instead, there was specialized reimbursement for end-stage renal disease. (8/22/06 Heggie Dep. 25:19-26:3, Ex. 35.)

13. Alternate Site Product Sales and Home Infusion Services together accounted for about 5% of total HPD revenues. (6/3/08 Gonzalez Dep. 125:3-6, Ex. 28.)

14. Alternate Site Product Sales concentrated on sales of HPD products to non-hospital providers, both individually and through group purchasing organizations ("GPOs"). (7/12/05 Baker Dep. 9:6-9, Ex. 3; 7/18/07 Leone Dep. 148:14-149:1, Ex. 45.)

15. Home Infusion Services, a small group with fewer than 40 customers, was not sales-oriented. (6/28/07 Kreklow Dep. 273:10-274:10, Ex. 43; 10/11/07 Rodman Dep. 524:10-18, Ex. 64; 3/31/08 Sellers Dep. 457:15-458:6, Ex. 76; 2/13/07 Sellers Dep. 210:2-16, Ex. 72.)

16. Home Infusion Services offered a variety of services—including business counseling, training, and help with claims submissions—to providers interested in starting up home infusion therapy operations. (3/16/08 Sellers Dep. 255:9-256:2, Ex. 75; 6/28/07 Kreklow Dep. 268:5-15, Ex. 43; 6/12/07 Brincks Dep. 166:23-167:2, Ex. 11; 10/28/04 Sellers Dep. 43:7-17, Ex. 70.)

17. Customers could pick and choose which of Abbott's services to employ. (3/16/08 Sellers Dep. 255:9-256:2, Ex. 75; 6/28/07 Kreklow Dep. 268:5-15, Ex. 43; 2/07/08 Kreklow Dep. 72:9-73:15, Ex. 44.)

18. Home Infusion Services was in part a means to allow Abbott to expand its presence in the field of home infusion therapy. (1/17/08 Leone Dep. 194:7-21, Ex. 45; 4/19/07 Snead Dep. 132:5-133:15, Ex. 78.)

19. For its services to customers, Abbott was paid either at a per diem rate, or based upon a percentage of the amounts collected from third party payers. (6/28/07 Kreklow Dep. 277:7-17, Ex. 43; 6/02/05 Tobiason Dep. 50:4-25, Ex. 82.)

20. During part of the claims period (1991-2001), Abbott owned and operated three home infusion pharmacies. (3/28/07 Tobiason Dep. 216:7-10, Ex. 83; 6/28/07 Kreklow Dep. 56:7-12, Ex. 43; 3/31/08 Sellers Dep. 485:4-18, Ex. 76.)

21. The Abbott-owned pharmacies were located in New Jersey, Los Angeles, and Chicago, and were closed in about 1996, 1998, and 2001, respectively. (6/28/07 Kreklow Dep. 56:7-12, Ex. 43; 3/31/08 Sellers Dep. 485:4-18, Ex. 76.)

22. In 1998, Abbott decided to discontinue Home Infusion Services. (12/20/05 Sellers Dep. 72:19-73:4, Ex. 71; 2/14/07 Sellers Dep. 414:11-415:2, Ex. 73.)

23. The decision to close Home Infusion Services was made because, among other things, the business model was outside Abbott's core business of pharmaceutical development and sales and because the business was, at best, only marginally profitable. (6/03/08 Gonzalez Dep. 172:9-173:6, Ex. 28.)

24. Home Infusion Services was phased out gradually, to allow the existing contracts to be honored through their completion. (2/14/07 Sellers Dep. 414:11-415:2, Ex. 73.)

25. Home Infusion Services closed in 2001. (11/01/07 Sellers Dep. 68:14-18; 124:4-9, Ex. 74.)

B. Abbott Priced The Subject Drugs Without Any Intention To Influence Medicare Or Medicaid Payment Levels.

1. HBS (Not Alternate Site) Set List Prices For The Subject Drugs.

26. Abbott had different price levels for the Subject Drugs for different types of customers. (2/28/08 Baker Dep. 415:13-417:11, Ex. 5; 12/6/05 Karas Dep. 116:2-6, Ex. 38; 3/31/08 Sellers Dep. 351:2-14, Ex. 76)

27. The lowest (best) price for the Subject Drugs was made available directly to the Government, and Abbott sold the Subject Drugs at this low price (far below the compendia AWP) to such governmental agencies as the Veteran's Administration and the Department of Defense. (3/16/08 Sellers Dep. 311:1-313:3, Ex. 75.)

28. Abbott also had a List Price for the Subject Drugs, which was also referred to as the Catalog or Direct Price. (8/23/07 Mershimer Dep. 87:6-11, Ex. 51.)

29. List Price was published by Abbott in pricing catalogs. (4/24/07 Eichorn Dep. 39:13-15, Ex. 22; 12/6/05 Karas Dep. 56:21-59:8, Ex. 38.)

30. List Price was the highest price for the Subject Drugs that was available in the marketplace. (3/16/2008 Sellers Dep. 261:22-262:14, Ex. 75; 8/23/07 Mershimer Dep. 288:20-289:4, Ex. 51; 4/24/07 Eichorn Dep. 145:22-146:2, Ex. 22.)

31. List Price was the price available to customers who did not have a negotiated contract with Abbott. (8/23/07 Mershimer Dep. 85:19-1, 287:3-288:11, Ex. 51; 3/31/08 Sellers Dep. 604:3-9, Ex. 76; 4/23/07 Baker Dep. 281:2-282:14, Ex. 4.)

32. Because most of Abbott's sales of the Subject Drugs were made through negotiated contracts, there were relatively few sales at List Price. (3/16/08 Sellers Dep. 57:1-58:14, Ex. 75.)

33. List Price sales, though not common, were valuable to Abbott, since they comprised the highest profit margin of any sales. (3/16/08 Sellers Dep. 57:1-9, Ex. 75; 4/24/07 Eichorn Dep. 74:13-75:14, Ex. 22; 8/29/07 Karas Dep. 63:18-64:22, Ex. 39.)

34. These sales sometimes occurred in situations where a competitor might have a supply shortage and be unable to fill its customers' needs, allowing Abbott to make opportunistic sales at the high List Price as those customers sought to cover the shortage. (3/16/08 Sellers Dep. 288:14-289:16, Ex. 75; 5/17/07 Sebree Dep. 51:13-52:10, Ex. 69; 8/29/07 Karas Dep. 33:7-19, Ex. 39.)

35. In addition, List Price was useful to Abbott because it gave customers an incentive to contract with Abbott (to obtain a lower price for generics) and it served as the

pricing point for proprietary products. (8/23/07 Mershimer Dep. 85:2-86:12, Ex. 51; 9/13/07 Robertson Dep. 142:12-143:4, Ex. 65)

36. In the early 1980s, Ven-A-Care's former President Luis Cobo, then-owner of a retail pharmacy, did not have a contract with Abbott for saline solution (one of the Subject Drugs). When one of Cobo's pharmacy customers asked to order a small quantity of saline, Mr. Cobo was required by Abbott to pay List Price and purchase an entire case. (1/8/08 Cobo Dep. 132:13-136:8, Ex. 16.)

37. List Prices for the Subject Drugs were set by HBS. (3/16/08 Sellers Dep. 97:20-99:12, Ex. 75; 8/23/07 Mershimer Dep. 81:11-22, Ex. 51; 5/17/07 Heggie Dep. 202:6-18, Ex. 34.)

38. Alternate Site had no role in setting List Prices. (3/16/08 Sellers Dep. 273:18-275:2, Ex. 75; 8/23/07 Mershimer Dep. 81:11-22, Ex. 51; 5/17/07 Heggie Dep. 202:6-18, Ex. 34.)

39. List Prices were not set by reference to, or in order to influence, the AWPs for the Subject Drugs. (3/16/08 Sellers Dep. 163:10-165:22; 169:17-170:14; 207:2-19; 216:20-217:3; Ex. 75; 3/31/08 Sellers Dep. 369:17-370:14; 391:1-12; 421:2-11, Ex. 76; 4/24/07 Eichorn Dep. 83:22-84:3, Ex. 22.)

40. During the period 1991-1999, List Prices for the Subject Drugs were adjusted approximately annually to reflect changes in the Consumer Pricing Index. (3/16/08 Sellers Dep. 98:20-99:9, Ex. 75; 8/23/07 Mershimer Dep. 45:3-46:2; 319:2-7, Ex. 51; 8/29/07 Karas Dep. 32:23-33:4, Ex. 39.)

41. This annual adjustment typically resulted in an increase in the List Prices of about 3-5%. (3/16/08 Sellers Dep. 100:17-22; 104:1-12, Ex. 75; 4/24/07 Eichorn Dep. 77:17-78:1, Ex. 22.)

2. HBS (Not Alternate Site) Reported Prices To The Compendia

42. HBS was responsible for reporting prices for the Subject Drugs to the various third-party pricing compendia. (3/16/08 Sellers Dep. 94:21-95:22; 135:8-12, Ex 75; 2/13/07 Sellers Dep. 140:21-141:2, Ex. 72; 5/30/07 Cicerale Dep. 14:11-22; 59:20-60:4, Ex. 13.)

43. Alternate Site also had no role in reporting prices for the Subject Drugs to the various publishing compendia. (2/13/07 Sellers Dep. 167:23-168:11; 175:2-24, Ex. 72; 3/16/08 Sellers Dep. 129:3-15, Ex. 75.)

44. HBS accurately reported to the compendia Abbott's List (Direct) price and its published Wholesale Acquisition Cost (WAC) for the Subject Drugs. (3/16/08 Sellers Dep. 93:6-94:16, Ex. 75; 5/30/07 Cicerale Dep. 60:5-10; 61:18-62:1, Ex. 13; Ex. 125 (Cicerale Ex. 925).)

45. HBS did not provide to the compendia an AWP or a "suggested" AWP for the Subject Drugs. (3/16/08 Sellers Dep. 204:5-18, Ex. 75; 3/31/08 Sellers Dep. 370:4-14, Ex. 76; 5/30/07 Cicerale Dep. 87:6-8; 137:17-20; 159:20-23, Ex. 13; Ex. 127 (2003 HPD Direct and Wholesale Price Changes); Ex. 128 (2003 HPD Drug Wholesaler Price Catalog); Ex. 129 (2003 HPD Price Catalog).)

46. The 2003 Red Book policy stated that "[w]hen the manufacturer does not provide an AWP or markup formula from which AWP can be calculated, the AWP will be calculated by applying a standard 20% markup over the manufacturer-supplied WAC. If a WAC is not provided, the standard markup will be applied to the DIRP." (Ex. 126 (2003 Red Book Policy).)

47. HBS representatives reported List Price and WAC to the compendia because that is what they believed was requested. (3/16/08 Sellers Dep. 93:6-94:16, Ex. 75; 2/13/07 Sellers Dep. 168:12-21; 170:25-72:9; 178:14-21, Ex. 72.)

48. When Abbott discussed with First Data Bank the issue of price reporting, FDB representative Kaye Morgan (who was responsible for the pricing information that FDB published) stated that FDB expected Abbott to report its highest, undiscounted price. (8/27/07 Morgan Dep. 28:19-29:3, Ex. 55; 10/25/07 Tootell Dep. 80:1-21, Ex. 84.)

49. Before working at FDB, Ms. Morgan was employed by Abbott from 1975-1999. (8/27/07 Morgan Dep. 27:17-23, Ex. 55.)

50. Ms. Morgan was familiar with Abbott's pricing, including the List Price for Abbott's products. (11/13/02 Morgan Dep. 50:23-51:15; 56:1-4, Ex. 56.)

3. Like Others In The Pharmaceutical Industry, Abbott Did Not Understand That The Compendia AWP Was Supposed To Be An Actual Average Market Price.

51. During the claims period, Abbott did not understand AWP as published in the various compendia to mean an actual average market price. (8/27/09 Sellers Decl. ¶¶ 7, 10-11, Ex. 89.)

52. There was no uniform understanding of AWP within the relevant division of Abbott. (8/27/09 Sellers Decl. ¶ 11, Ex. 89.)

53. As numerous witnesses testified, Abbott did not set AWP for the Subject Drugs. (12/20/05 Sellers Dep. 153:4-12; 157:10-158:16, Ex. 71; 1/30/08 Haines Dep. 141-49, Ex. 31; 2/7/08 Kreklow Dep. 347:2-7, Ex. 44.)

54. Abbott did not publish or report AWP for the Subject Drugs. (8/27/09 Sellers Decl. ¶ 12, Ex. 89; 8/29/07 Rodman Dep. 25:2-4, Ex. 63.)

55. Abbott did not charge AWP for the Subject Drugs to any of its customers. (2/7/08 Kreklow Dep. 131:2-7, Ex. 44; 11/1/07 Sellers Dep. 131:6-133:22, Ex. 74.)

56. Plaintiffs deposed more than 65 persons who were formerly employed in Abbott HPD.

57. Fewer than 15 of these witnesses actually understood how the compendia calculated AWP for the Subject Drugs, namely by applying a markup to Abbott's List Price. (*E.g.*, 10/25/07 Tootell Dep. 296:21-297:22, Ex. 84.)

58. A few others understood generally that AWP was published by the compendia and had some relationship to Abbott's prices, but did not know the precise nature of that relationship. (2/26/08 Cannon Dep. 391:1-393:3, Ex. 12; 10/9/07 Robertson Dep. 530:9-531:4, Ex. 66.)

59. Many others testified that they did not really understand the nature of AWP at all, except that it stood for "average wholesale price." (2/28/08 Miser Dep. 201:4-17, 214:3-4, 230:9-15, Ex. 54; 2/13/08 Rayford Dep. 104:7-17; 120:4-10, Ex. 57; 2/21/08 Aldy Dep. 157:1-158:3; 332:2-337:7, Ex. 1; 3/13/08 Debbie Johnson Dep. 81:9-82:3, Ex. 37; 9/7/07 Rotz Dep. 152:5-8, Ex. 67.)

60. One witness, Bruce Rodman, testified that at one time he assumed AWP was a literal average price, but as he learned more about it later, he discovered that it was merely a benchmark, undiscounted price. (8/29/07 Rodman Dep. 21:17-27:1, Ex. 63.)

61. At most, Abbott understood AWP to be an undiscounted price calculated by the compendia. (8/27/09 Sellers Decl. ¶ 11, Ex. 89.)

4. Abbott Truthfully Reported Actual Market Prices For The Subject Drugs To The Government Quarterly During The Claims Period.

62. Abbott reported Average Manufacturers Price ("AMP") for the Subject Drugs directly to the Government on a quarterly basis. (6/27/07 Lyman Dep. 36:3-20, Ex. 50.)

63. In all, Abbott reported its AMP for the Subject Drugs directly to CMS about 40 times during the claims period.

C. Abbott Did Not Market The Spread.

64. Rather than focusing on individual products, Alternate Site Product Sales field representatives marketed the entire HPD product portfolio as a package. (3/18/08 Blackwell Dep. 221:13-222:9, Ex. 9; 5/3/07 Balzer Dep. 51:14-22, Ex. 7; 10/30/07 Harling Dep. 39:1-8, Ex. 32; 1/17/08 Leone Dep. 305:10-19, Ex. 45; 3/5/09 Reisetter Expert Rep. ¶ 28, Ex. 58; Sales Training Module, Ex. 96.)

65. The sales representatives were trained to market based upon the depth and breadth of the product portfolio, quality, reliability of supply, customer service, and competitive price. (3/18/08 Blackwell Dep. 221:13-222:9, Ex. 9; 5/3/07 Balzer Dep. 51:14-22, Ex. 7; 10/30/07 Harling Dep. 39:1-8, Ex. 32; 1/17/08 Leone Dep. 305:10-19, Ex. 46; 3/5/09 Reisetter Expert Rep. ¶ 28, Ex. 93; Sales Training Module, Ex. 96.)

66. Sales representatives were *not* instructed to market products based upon any "spread" between the customer's acquisition cost and the payment amount the customer would receive for dispensing that product from Medicare or Medicaid. (3/18/08 Blackwell Dep. 221:13-222:9, Ex. 9; 5/3/07 Balzer Dep. 51:14-22, Ex. 7; 10/30/07 Harling Dep. 39:1-8, Ex. 32; 1/17/08 Leone Dep. 305:10-19, Ex. 46; 3/5/09 Reisetter Expert Rep. ¶ 28, Ex. 93; Sales Training Module, Ex. 96.)

67. To the contrary, many former sales representatives deposed by plaintiffs testified that they understood it was Abbott's practice not to market the spread. (3/31/08 Sellers 348:9-17, Ex. 76; 4/23/08 Zackowski 148:8-17, Ex. 88.)

68. Numerous others testified that the issues of AWP and spread were not at all relevant to their work, and that they did not discuss those issues with their customers. (3/18/08 Blackwell Dep. 221:13-222:9, Ex. 9; 5/3/07 Balzer Dep. 51:14-22, Ex. 7; 10/30/07 Harling Dep. 39:1-8, Ex. 32; 1/17/08 Leone Dep. 305:10-19, Ex. 46; 3/5/09 Reisetter Expert Rep. ¶ 28, Ex. 93; Sales Training Module, Ex. 96.)

D. When Abbott Discovered The Inadvertent Disparity Between Its List Price And Its Contract Prices, It Took Steps To Reduce That Disparity.

69. Throughout the 1990s, as a result of increased competition in the marketplace and other changes in the manner of sales of generic drugs in the industry generally, sales at prices set by contract with particular customers accounted for a substantial and growing portion of HPD's business. (5/17/05 Balzer Dep. 38:1-39:20, Ex. 6; 3/25/08 Kassak Dep. 126:13-127:8, Ex. 40.)

70. HPD customers purchasing through a contract with Abbott were able to negotiate prices below the published List Prices. (3/26/08 Kelly Dep. 91:15-93:12, Ex. 41; 4/26/07 Krajewski Dep. 116:8-117:5, Ex. 42; 8/31/07 Longley Dep. 248:8-250:4, Ex. 47; 5/13/07 Lyjak Dep. 89:10-91:10, Ex. 49; 3/17/08 Renick Dep. 90:13-92:9, Ex. 59.)

71. Over these years, contract prices for HPD generic products generally decreased due to market forces, particularly as more generics flooded the marketplace and customers began to band together into large GPOs, increasing their bargaining power. (3/16/2008 Sellers Dep. 58:21-59:13; 103:13-21; 214:7-21, Ex. 75; 3/28/08 Young Dep. 67:19-68:14, Ex. 86; 10/30/07 Harling Dep. 40:11-13, Ex. 32.)

72. Over time, this fierce competition resulted in a gradual widening of the difference between negotiated contract prices and List Prices. (3/16/2008 Sellers Dep. 58:21-59:13, Ex. 75; 6/3/2008 Gonzalez Dep. 94:1-6, Ex. 28.)

73. Beginning in or about late 2000, Abbott undertook a review of pricing practices within HPD, and consequently discovered the difference that had gradually grown over the years between List Prices and negotiated contract prices for HPD products. (3/16/2008 Sellers Dep. 50:11-16; 60:14-17; 68:4-5; 74:5-10, Ex. 75.)

74. This disparity was unintentional, and was not designed by Abbott to influence Government payment levels under the Medicare or Medicaid programs. (3/16/2008 Sellers Dep. 58:21-59:13; 59:19-60:3, Ex. 75)

75. As part of this internal review, Abbott considered many factors, including its own business, the industry generally, and the overall discourse in Congress and elsewhere about pharmaceutical issues. (3/16/2008 Sellers Dep. 66:16-17; 69:6-14; 70:9-12; 71:5-10, Ex. 75)

76. Viewing the totality of the circumstances, a decision was made to reduce the List Prices for certain HPD products, thereby decreasing the unintended disparity between List Prices and negotiated contract prices. (3/16/2008 Sellers Dep. 67:13-15, Ex. 75.)

77. Abbott made these List Price adjustments effective in or about May 2001. (3/16/2008 Sellers Dep. 80:13-81:2, Ex. 75.)

E. The Alleged Business Practices Highlighted By The Government Merely Emphasize The Many Disputed Issues Of Fact In This Case.

78. In late March 1995, after the annual catalog price changes had been made, HBS lowered the List Prices for three NDCs of Vancomycin. (3/31/08 Sellers Dep. 425:5-426:1, Ex. 76; Response to TX Interrog. 12, Ex. 97.)

79. About two months later, HBS raised those List Prices back up to the price level in Abbott's 1995 Catalog. (3/31/08 Sellers Dep. 425:5-426:1, Ex. 76; Response to TX Interrog. 12, Ex. 97.)

80. Abbott witnesses, including its corporate designee, have testified that the prices were raised back up, among other reasons, because HBS's practice is to make List Price changes only as part of the traditional annual cycle, and the March 1995 changes were outside that practice. (3/31/08 Sellers Dep. 428:3-13, Ex. 76; 4/24/07 Eichhorn Dep. 185:19-186:5, 199:10-200:7, Ex. 22.)

81. The Medicare Working Group at Abbott involved a few persons within the company who, in the time period of about fall of 1996 to mid-year 1997, reviewed various pending legislative initiatives relating to Medicare and Medicaid. (8/9/07 Rieger Dep. 21:1-10, 29:3-22, Ex. 62; 7/30/07 Miller Dep. 55:5-9; 56:13-57:11, Ex. 52.)

82. The Medicare Working Group merely reviewed legislative initiatives; it never took any action on any such initiatives. (8/9/07 Rieger Dep. 342:8-13, Ex. 62; 7/30/07 Miller Dep. 237:1-9, Ex. 52.)

II. ADDITIONAL ISSUES OF MATERIAL FACT REGARDING FALSITY AND SCIENTER

A. The Government Knew The Actual Market Prices Of The Subject Drugs

83. OIG documents from a 1991 invoice study showed that dialysis clinics were purchasing Vancomycin at discounts of about 80% off of AWP. For example, OIG notes reflect that in 1991, Abbott's AWP for Vancomycin was $24.88. (Ex. 98 (HHD200-0016).) One of the collected invoices from the same year reflects sales of Vancomycin at $4.59—a discount of nearly 82%. (Ex. 99 (HHD200-1431.))

84. Dr. Bruce Vladeck, HCFA Administrator from May 1993 to September 1997 testified that he reviewed articles published *Modern Healthcare* magazine during the 1980s which discussed discounts on basic infusion products and sterile supplies as high as 99%. (5/4/2007 B. Vladeck Dep. 144:22-145:19, Ex. 87.) Dr. Vladeck provided the following testimony:

> A. Well, I actually—in the 1980s, I believe, when I was first becoming involved in some of these issues in health care economics was the first development of hospital group purchasing operations, and I recall—and the first widespread circulation of the—of "Modern Healthcare," the magazine, and I recall monthly headlines in "Modern Healthcare" about group purchasing operations being—achieving discounts of 98 and 99 percent in their purchase of basic infusion products and sterile supplies. So, my perception was that on the supply market, which, again, I understood and still would contend is actually a separate market from the pharmaceutical market that list prices, are essentially entirely meaningless and that only the weakest and smallest scale buyers pay anything close to it.
>
> Q. And so, as of 1993, for example, would you be surprised if a single bag of sodium saline solution sold to a provider who bought maybe five would pay $10 per bag, and a large purchaser who bought a very large volume would pay less than a dollar?
>
> MS. BROOKER: Objection. Form.
>
> A. I would not have been surprised.

(*Id.* at 145:09-146:12.)

85. Paul Chesser was the OIG agent who analyzed invoices pulled in conjunction with the 1994 AWP study. He testified that he found "significant discounts" on injectable solutions—at a "90 plus percent" discount from AWP. (Chesser Dep. at 626:6-630:12, Ex. 14.) Mr. Chesser provided the following testimony:

> Q. Would it surprise you to see discounts in the 90 percent plus range for these injectables?
>
> A. No. It was very common.

(*Id.* at 630:5-7.) Other work papers obtained for this 1994 study showed acquisition prices for the four drugs at issue in this litigation – Vancomycin, sterile water, sodium chloride, and dextrose. (Dkt. No. 6187 at ¶ 57, Ex. BX.)

86. On August 30-31, 1994, representatives from OIG, HCFA, and ten State Medicaid programs met in Richmond, Virginia to discuss OIG's plan to conduct a nationwide audit surveying the difference between the invoice price for drugs and AWP, for Medicaid providers. (Ex. 133 (Abbott Ex. 581).) OIG prepared a "Record of Discussion" of that meeting. (*Id.*) OIG's Record of Discussion includes the following statement:

> They stated that we should include a fifth category of pharmacies to include non-traditional retail pharmacies such as hospitals, home IV, nursing homes, physicians etc . . . The State officials believed that these pharmacies purchased at substantially bigger discounts than traditional retail pharmacies.

(*Id.* at 2-3.)

87. In 1996, *Barron*'s published an article called "Hooked on Drugs," which reported that Abbott's vancomycin was sold at 74% below AWP. (Ex. 100 at R2-038154.) (Abbott Ex. 0016.) The article also stated:

> This sampling showed that for single-source drugs still enjoying patent protection . . . , true wholesale prices are generally 10%-20% below published AWPs. But for generic drugs, nearly every manufacturer's price was 60%-85% below the published average wholesale price
>
> The pricing unreality is even worse for intravenous nutritional and solutions, a category dominated by Abbott Laboratories and Baxter International. Catalog wholesale prices for these items are, on average, 80%-98% below those companies' AWPs.

88. In December 1997, OIG reported that GPO prices for Vancomycin ranged from $2.02 to $6.99, while the AWP was about $10.07. (Ex. 101 at A-1 to B-2.) (Abbott Ex. 002.)

89. The record evidence developed in this case shows, overwhelmingly, that relevant state and federal officials were aware of that AWPs reported in the compendia was not a reliable indicator of acquisition cost for generic drugs, and that large percentage discounts were commonplace. (*See* Defs. Comb. Rule 56.1 Add'l SOF ¶¶ 1-4.)

B. The Government's AWP Policies

1. Home-Infusion Cross Subsidization

90. Between 1987 and until the mid-1990s, a publication titled the *Medicaid Pharmacy Bulletin* was published with input from state Medicaid pharmacy officials. The *Medicaid Pharmacy Bulletin* was designed "to assist the Medicaid pharmacy community in keeping abreast of the latest program management practices and developments in health care policy that affect Medicaid pharmacy." (Ex. 104 (Abbott Ex. 292).) In its January-February 1987 issue, the *Medicaid Pharmacy Bulletin* included an article titled "Medicaid Reimbursement for the Pharmacy Component of Home I.V. Therapy." (*Id.*) Among other things, that article stated:

> The Establishment of a Fair and Reasonable Pricing Methodology for Home I.V. Products is a Major Concern of Most State Medicaid Programs.
>
> One of the major obstacles to the development of adequate home I.V. pricing methodologies the fact that the dispensing of home I.V. Medications is more complex than the dispensing of other outpatient drugs.
>
> * * *
>
> Providers and Pharmacist Consultants Concur That it is Not Appropriate to Apply the Same Ingredient-Based Pricing Mechanisms to Home I.V. Medications as Those Applied to Other Outpatient Drugs.
>
> For lack of a better alternative, some state Medicaid programs use the same ingredient-based formula they apply to other legend drugs when calculating reimbursement for home I.V. medications.

> Most pharmacist consultants are not convinced that this process reflects actual provider costs for home I.V. reimbursement. Home I.V. treatments are frequently a combination of multiple drug entities, dispensed in varying doses and administered several times daily. . . . It is, therefore, difficult to estimate, based on single, daily or even weekly administrations, the purchase prices providers are paying with volume and trade discounts. These discounts are generally not revealed in drug pricing publications such as the *Red Book*, the *Blue Book* and *Medispan*. Consequently, programs are reluctant to increase reimbursement for home I.V. medications, suspecting that reported costs for these substances may already be exaggerated.

(*Id.* at 2-3). The table contained within the article indicated that Oregon based its reimbursement for intravenous prescriptions at "80% of usual and customary charge," that Montana paid the "lower of usual and customary charge or Up to 2 ½ times the cost of ingredients plus a $2.00-$3.75 dispensing fee." (*Id.* at 4.) The chart also indicated that Massachusetts paid a percentage "mark up" on the drug depending on the cost of the drug, whereby lower-priced products received a higher-percentage mark up. (*Id.*) State Medicaid official Cynthia Denemark, Delaware's Pharmacy Consultant, testified that the *Medicaid Pharmacy Bulletins* were "valuable publications." (12/10/08 C. Denemark Dep. at 349:13-351:01, Ex. 18.) Former Maryland Medicaid official Joseph Fine also testified that the *Medicaid Pharmacy Bulletins* were a useful source of information containing very reliable information. (12/9/08 J. Fine Dep. at 82:16-83:10, Ex. 23.)

91. In 1999, under contract from the Louisiana Department of Health and Hospitals, Myers and Stauffer prepared a report analyzing the pharmacy dispensing costs and drug acquisition costs for providers serving Louisiana Medicaid beneficiaries. Myers and Stauffer found that "the costs to dispense I.V. prescriptions are not representative of the costs incurred by a general pharmacy" because "the activities and costs involved in filling I.V. prescriptions are significantly different." (Ex. 105 at 20-21 (Excerpts of Abbott Ex. 1051).) Myers and Stauffer

concluded that "[a]lthough typical dispensing fees reimburse less than the dispensing costs of I.V. pharmacies, they are generally able to break even based on the margin allowed on the ingredient cost reimbursement." (*Id.* at 21 n.8.)

92. In 2001, under contract from the Kentucky Department for Medicaid Services, Myers and Stauffer prepared a report on the cost of dispensing prescription medications to Kentucky Medicaid recipients. The report was titled "A Survey of Dispensing costs of Pharmaceuticals in the Commonwealth of Kentucky." In its analysis of pharmacy dispensing costs, Myers and Stauffer found that "pharmacies that dispense I.V. prescriptions as a significant part of their business can have dispensing costs far in excess of those found in a traditional pharmacy." (Ex. 106 at 20 (Excerpts of Abbott Hansen Ex. 6).) Pharmacists interviewed by Myers and Stauffer indicated that "the activities and costs involved in filling I.V. prescriptions are significantly different from the costs incurred by the typical retail (or long term care) pharmacy." (*Id.* at 19.) In 2001, the Kentucky Department for Medicaid Services reimbursed providers who administered intravenous prescriptions based on a fixed dispensing fee plus ingredient reimbursement formula. Myers and Stuffer concluded that "[a]lthough dispensing costs at intravenous pharmacies is well in excess of the current dispensing fee, this reimbursement methodology has been accepted by these pharmacies because the margin on ingredient reimbursement has allowed pharmacies to offset any shortfall from the dispensing fee." (*Id.* at 46.)

93. In 2002, under contract from the California Department of Health Services, Myers and Stauffer prepared a report titled "Study of Medi-Cal Pharmacy Reimbursement." (Ex. 107 (Excerpts of Abbott Schondelmeyer Ex. 4).) The report stated: "In every dispensing cost survey performed by Myers and Stauffer in which data on the provision of intravenous services was

collected, the provision of this service has been associated with higher dispensing costs. (*Id.* at 59.) Myers and Stauffer concluded that the average intravenous prescription "would yield a margin on ingredients of approximately $42." (*Id.* at 60.) The report stated: "This margin typically allows for adequate reimbursement of the pharmacy's dispensing cost. So long as the ingredient reimbursement rate remains at AWP minus 5% or any other relatively 'high' level, the need for the Department to set a separate dispensing fee for intravenous drugs is somewhat mitigated by the margins realized on ingredient reimbursement." (*Id.*)

94. Myers and Stauffer published other reports for state Medicaid programs that detailed the increased dispensing costs associated with the provision of home infusion and I.V. solutions. These include:

- Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the Commonwealth of Kentucky, October 2003 (Ex. 108 (Excerpts of Abbott Ex. 1110));
- Survey of Dispensing Costs in the State of Kansas, September 1999 (Ex. 109) (Excerpts Attached);
- Survey of Dispensing Costs in the State of Arkansas, June 2001. (Ex. 110) (Excerpts Attached);
- Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the State of California, December 2007 (Ex. 111 (Excerpts of Abbott Schondelmeyer Ex. 3));
- Analysis of Pharmacy Dispensing Fees for the Indiana Medicaid Program, August 2005 at 24-25. (Ex. 112 (Excerpts of Ex. Abbott Shirley-7)); and
- Determining the Cost of Dispensing Pharmaceutical Prescriptions for the Texas Vendor Drug Program, August 2002 (Ex. 113 (Excerpts of Abbott Ex. 21).)

95. On January 27, 2006, Abt Associates, Inc. prepared a report for The National Home Infusion Association (NHIA) titled "The Per Diem Costs of Home Infusion Therapy Services." (Ex. 114.) NHIA contracted with Abt Associates, Inc. to conduct a survey and analysis of the per diem costs associated with providing home infusion therapy services. The

report noted the difference in services necessary for home infusion therapy and found the average per diem cost for three hours of antibiotic therapy was $102. (*Id.* at 7.) The report further stated:

> It is noted earlier that services necessary for home infusion therapy are notably different than those provided from traditional community retail pharmacies. As compared to much lower dispensing fees typically reimbursed to traditional community retail pharmacies for filling prescriptions, the average direct cost for the delivery component alone was found to be $38.25. In addition to delivery, the many other incurred costs--referral processing, intake qualification and documentation setup, care coordination, verifying physician order set, sterile compounding, packaging, patient education, clinical monitoring, insurance administration, etc.—are reported in the per diem costs. (*Id.* at 7.)

96. H. Leo Sullivan, former Director of Pharmacy Services for Tennessee, testified:

> A. . . . So getting back to, to the MAC issue, some, sometimes for certain products in this arena, you would take that into account for the MAC. For example, I might say, I'm not paying for the tape that you use to hold the IV needle into place. I'm not paying for the IV needle or the tube set. I'm not going to—I don't want bills for that. I know you've got to do it to administer this drug. So we're going to add on the cost of this drug X, because I know this, this and this always goes with it, and I know there is a fixed cost for that, but I don't want five bills. I want 10 different places. Bill me for the drug. And I'll make sure that the—whatever the MAC is incorporates all your other costs. And you have to talk with providers and know what that is. I mean, you know.
>
> Q. So, in short, you would use the payment for the drug itself to cross-subsidize other things that might need to be paid to fairly—
>
> A. And that would include compounding.
>
> Q. And it may include nursing services that were not included, things of that nature?
>
> A. (Nodding yes.)
>
> Q. Did anyone in the federal government ever tell you that you were not allowed to do that?

A. No.

(3/12/08 H. Sullivan Dep. 153:20-155:04, Ex. 79.)

97. Benny Ridout, former North Carolina Medicaid Pharmacy Director, testified:

Q. You mentioned that it was common knowledge that Vancomycin had a spread, do I have that correct?

MS. HAYES: Objection to form.

A. Yes.

Q. When was it common knowledge that Vancomycin had a spread?

A. I don't remember the year, just like it was this, but I just remember that drug was one of the antibiotics.

Q. Do you recall whether it was similarly common knowledge that infusion products had spreads?

MS. YAVELBERG: Objection, form.

MS. HAYES: Objection, form.

A. We had no idea what the specialty pharmacists were paying for that drug, what kind of deals they struck with the manufacturers, but it was of their opinion of us that there was some kind of spread in there because of what they were able to do that a regular pharmacist couldn't do at AWP. You see, we still paid at AWP.

Q. What do you mean what they could do that other pharmacists couldn't?

A. Infusion drugs is a whole lot more than just putting a pill in bottle. You got to prepare. In fact, the pharmacists wanted a special fee to do this under-the-hood preparation, you know, also injection takes longer, you got to have syringe and all the stuff to do that. Of course they were shipping that on top of the cost to ship the product. If you add up all that extra cost in a regular pharmacy or regular pills, you know, you think well, how in the world can they afford to do this and accept that same price?

Q. What was your conclusion?

A. That somehow they were getting some kind of special deal back or discount from the manufacturers to be able to do it or

something. That was just my own personal feeling. How did they do it?

(12/5/08 B. Ridout Dep. 62:6-64:3, Ex. 61.)

98. M.J. Terrebonne, Louisiana Pharmacy Director, testified:

Q. If you look to the footnote 8 on page 21 of the Myers and Stauffer report—

A. Right.

Q. —that states—Would you read that into the record?

A. "Although typical dispensing fees reimburse less than the dispensing cost of I.V. pharmacies, they are generally able to break even based on the margin allowed on ingredient cost reimbursement."

Q. And do you have an understanding of—of what that's saying?

A. I believe what he's saying is that there's a margin on the ingredient side, so that's how they're generally able to dispense.

Q. And this is something that—that you would have read back in 1999; correct?

MR. FAUCI: Objection to form.

THE WITNESS: Probably.

BY MR. TORBORG:

Q. Okay. And if you disagreed with that footnote, would you have told Myers and Stauffer that?

A. Well, they were the surveyors, so they had the information. We were relying on—

Q. Well, was it your understanding, Miss Terrebonne, that because of the higher cost to dispense home I.V. drugs and the fact that Louisiana was only paying a $5.77 dispensing fee for those drugs, that the margin being earned on the ingredient cost was covering that cost to dispense?

MR. FAUCI: Objection to form.

THE WITNESS: Based upon the survey results, yes.

(11/7/08 M. Terrebonne Dep. 91:11-93:1, Ex. 81.)

99. In 1998, legislation was proposed in Florida to create a new reimbursement system for home infusion providers. Regarding that proposal, Jerry Wells, former Pharmacy Program Manager for Florida Medicaid, wrote:

> Intravenous / Intramuscular administration of drugs such as antibiotics, cancer chemotherapy, immune suppression agents and many others, during the past 6 years, has moved dramatically from the inpatient hospital environment to the patients home.
>
> * * *
>
> Cost savings resulting from reduced inpatient days are dramatic but result in increased costs for prescribed drugs. The current dispensing fee ($4.23) does not approach the cost of providing these services and no current reimbursement exists for ancillary supplies (syringes/needles, tubing, admixture bags, IV pumps, etc.). This bill will authorize establishing a distinct provider type for parenteral or infusion pharmacy services.

(Ex. 115 (Wells Ex. 1006).)

100. Mr. Wells understood that services provided by home infusion providers were significantly different than those provided by retail pharmacies. Mr. Wells testified:

> Q. What are some of the issues that you're referring to there when you talk about these square peg/round hole problems between infusion pharmacies and community pharmacies?
>
> A. Infusion pharmacies were involved in preparation of sterile product for injectible use, which is a little more involved than putting prescription tablets or capsules into a vial and dispensing in the community environment. There were some issues with disposal supplies that providers would like to be reimburse for and we had no provision to reimburse them for.

(12/15/08 J. Wells Dep. 125:12-126:1, Ex. 85.)

> * * *
>
> Q. What do you recall about those conversations with home infusion vendors in the 1990 time period?

> A. They were desirous of having infusion supplies, tubing, IV sets, butterflies, and that sort of thing, added as a reimbursable item under the prescription drug program, and because those products frequently did not have a national drug code, we didn't have any way to pay for them, and the DME, durable medical equipment supply program, would not pay for those by policy for patients that were over the age of 21.

(*Id.* at 129:19-130:8.)

> Q. And so while you didn't know the precise size of the margin on the drug ingredient reimbursement for home infusion pharmacies as of 1990, were you aware that to some degree those home infusion pharmacies were using profits on the drug ingredient side to offset additional costs in the dispensing of IV drugs?
>
> MS. ST. PETER-GRIFFITH: Object to the form.
>
> MS. WALLACE: Objection to form.
>
> MR. BREEN: Objection to form.
>
> THE WITNESS: I had been told that by two or three of those providers.
>
> BY MR. COOK:
>
> Q. Did you believe them?
>
> MS. ST. PETER-GRIFFITH: Object to form.
>
> MS. WALLACE: Objection to form.
>
> THE WITNESS: I had no reason not to believe them. I felt like they were being honest and...

(*Id.* at 132:3-133:1.)

101. Mr. Dubberly from Georgia Medicaid testified that Georgia knew was providing providers a profit margin:

> Q. Mr. Robben asked you some questions about the interplay between the -- the reimbursement of ingredient costs and the reimbursement for dispensing costs. Do you remember those questions, sir?

A. Yes.

Q. And I believe you said that -- that the Georgia Medicaid program understood that -- that they were providing a -- a profit margin to providers in reimbursing them for the ingredient costs; is that right?

MR. LAVINE: Object to form.

A. Yes. I acknowledged that there was profit margin in the current ingredient cost formula.

Q. (By Mr. Cole) And that if -- if that margin were to be eliminated, then Georgia would have to pay a higher dispensing fee to providers to make up for the lost margin on the ingredient cost side; is that fair?

MR. LAVINE: Object to form.

A. That's fair.

Q. (By Mr. Cole) And would that approach apply even more in the home infusion setting where you have pharmacies incurring even greater dispensing costs?

MR. SULLIVAN: Object to form.

A. No. That equation that we spoke about was only looking at the acquisition cost of the drug, not the -- the overhead.

Q. (By Mr. Cole) What do you mean by that?

A. When we were talking about the fact that there was margin in the ingredient cost of the drug, the cost by which the pharmacy purchased the drug -- when you're talking -- you're talking about an additional cost to dispense. So changing the ingredient cost and getting that more in line with the actual acquisition cost would not necessarily mean that we would adjust and make a differential for home health or for long-term care or any other provider. We may review that, but it -- it would actually be an additional exercise.

Q. Going back to the let's say mid to late '90s time period when the dispensing fee paid by Georgia Medicaid was roughly in the $4 to $4.63 range, do you believe that the dispensing fee paid by Georgia Medicaid during that time frame was adequate to cover pharmacies' dispensing costs?

A. No.

> Q. And in the home infusion setting -- if at that level -- if -- if the $4.63 was not adequate to cover a retail pharmacy's dispensing costs, then I assume you would agree with me that it certainly did not cover the dispensing costs of a home health pharmacy or some other pharmacy that administered prescriptions in the home infusion setting.
>
> MR. SULLIVAN: Object to the form.
>
> A. Agreed.
>
> Q. (By Mr. Cole) Is it fair to say, Mr. Dubberly, that in assessing whether to increase the dispensing fee, it has been the policy of the Georgia Medicaid program to consider the margin on ingredient cost?
>
> MR. LAVINE: Object to form.
>
> A. It's been the practice.

(12/15/08 Dubberly Dep. 314:3-317:7, Ex. 20.)

102. Missouri is one of a number of states that implemented the DOJ AWPs, but later reversed its decision. In June of 2002, Missouri's Office of State Auditor wrote a performance audit titled "Cost Containment for State Drug Expenditures." (Ex. 116.) The report contained a discussion of Missouri's use of the DOJ AWPs, including the following language:

> Within 2 months of Department of Justice notice of the more accurate average wholesale prices, Utah officials began using the lower drug prices with new dispensing fees. With the help of infusion specialty providers, Utah officials categorized the 437 drugs into 5 groups appropriate to the preparation and overhead costs for the product. The new dispensing fees set up for drugs in 4 of the 5 categories ranged from $8.90 to $33.90 per prescription.
>
> Missouri officials initially implemented the more accurate prices for provider reimbursement using the normal $4.09 dispensing fee, which was not designed to cover these drugs. Division officials reversed the decision after home infusion providers threatened to cease services due to insufficient dispensing fees. Provider personnel admitted the former reimbursement rates exceeded their product acquisition costs, but they used the excess reimbursement to offset the higher dispensing costs of home infusion drugs. Division officials indicated they plan to use these lower prices again after determining adequate compensation for home infusion

> services. While no implementation date has been set, the Division Director stated the necessary changes to implement these prices would be part of the division's fiscal year 2004 budget proposal.

(*Id.* at 9.)

103. California Medicaid did not adopt the DOJ AWPs. A document produced by California contains the following language regarding why California did not adopt the prices:

- "Accepting these new AWP's as the basis for provider reimbursement in Medi-Cal is a serious policy consideration. This change would result in dramatic decreases in the reported AWP for approximately 400 drugs—decreases of as much as 80% in some cases. The new AWP reductions apply to drugs which are usually administered in physicians' offices or clinics. However, the same drugs are often administered at patients' homes via pharmacy dispensing and home health care administration."

- "The Department is concerned that providers affected by the new AWPs may discontinue serving FFS Medi-Cal patients if the new prices are implemented. If this occurs, patients would either not have access to these important drugs or patients would be directed to a hospital to obtain them."

- "Department staff recently participated in a national teleconference on this subject involving other state Medicaid pharmacy programs. Many pharmacy program administrators indicated that they were not implementing the new AWPs at this time because of concerns over provider discontinuation and resultant patient access problems."

- "We recommend that Medi-Cal not implement the new price reporting mechanism due to the serious impact on both the providers and beneficiaries."

(Ex. 117 (Gorospe Ex. 14 (3/19/08 Dep).) California's Kevin Gorospe confirmed that California did not adopt the DOJ AWPs out of concerns over access. (3/19/08 Gorospe Dep. 198:7-201:14, Ex. 29.)

104. On June 22, 2000, Minnesota's Cody Wiberg sent an e-mail to the National Medicaid Pharmacy Administrators wherein he stated:

> While the legislators did not define AWP, we believe that their intent was to use "AWP" to mean a single estimate of wholesale price as published in a compendia such as Redbook or First DataBank. My understanding is that FDB is now publishing two sets of "AWPs" for the 428 drugs in question – one for Medicaid

> agencies and one for everything else. The fact that the legislators chose to estimate actual acquisition costs at AWP-9% indicates that they were aware that the single, published AWP was actually higher than the price for which most pharmacies could buy drug products. Had they known that AWP would be reduced to AAC, they would not have established a 9% discount off of AWP.
>
> * * *
>
> Some public and .private third party payers have purposely kept the dispensing fee low precisely because there is a spread between AWP and AAC. In fact, when pharmacy organizations have sought an increase in dispensing fees, the AWP spread has been pointed out to legislators. It is true that ingredient reimbursement is supposed to be based on estimated acquisition cost. The ancillary costs of dispensing the drug are supposed to be accounted for by the dispensing fee. If the AWP spread disappears, the dispensing fee may have to be increased, especially for many of the 428 drugs currently in question. Many of these drugs require some type of compounding or other preparation.

(Ex. 118 (Abbott Ex. 492).)

105. Effective April 1, 2001, Utah implemented special category dispensing fees for NDCs covered by the revised pricing issued by the United States Department of Justice. (Ex. 119 (HHC014-0833).) An April 2001 document titled "The Amber Sheet" prepared by the Utah State Medicaid DUR Committee stated:

> MULTIPLE DISPENSING FEES ASSOCIATED WITH HOME INFUSION PHARMACY SERVICES. The U.S. Department of Justice (DOJ) as part of a legal process, has established 'true' AWP for 437 NDC specific products and has directed the Division to implement this price list. Home infusion pharmacy services have low volume and high expenditures. The DOJ's price list place the 'true AWP' close to actual acquisition costs, thus eliminating the 'spread' or profit that pharmacies have enjoyed for years.

(*Id.*)

106. In May and September 1993, there were hearings before the House of Representatives Subcommittee on Oversight and Investigations regarding Medicare's

reimbursement for home drug infusion therapies. (Ex. 120 (excerpts).) Testimony was provided by individuals representing home infusion interest groups, such as the National Alliance for Infusion Therapy, as well as government officials from the Office of Inspector General, the Department of Health and Humans Services, and HCFA. (*Id.* at III.)

(a) Congressman Dingle stated that "[t]he Medicare program has a convoluted system for paying for [home infusion] services. Some are paid for under Part A, some under Part B. Some are billed as durable medical equipment, some under laboratory services and some under drug provisions. Obviously, it is a situation where it is difficult to keep track of what is going on." (*Id.* at 2.)

(b) Elaine J. Power, Senior Analyst, Health Program Office of Technology Assessment testified that "Medicare has no explicit benefit that covers home drug infusion therapy. Components of this therapy are sometimes covered through various existing Medicare benefits. Because this coverage is fragmented, the amount that Medicare spends on home drug infusion therapy is unknown, and the quality of the overall infusion related services received by Medicare beneficiaries cannot be evaluated or monitored." (*Id.* at 26.) Ms. Power further stated:

> For Medicare, the fact that Medicare does not cover it-probably the most significant effect is the fact that there is not any of the overlying Federal regulatory structure that tends to come along when Medicare starts covering something. So, for example, under the Medicare Catastrophic Act, where home I.V. drug therapy was going to be an explicit covered benefit, there were going to be regulations that would have defined what a home IV provider was and what kinds of services they could provide and so forth. So, the fact that Medicare does not explicitly recognize the benefit means that that regulatory structure does not exist at the Federal level.

(*Id.* at pg. 43.)

(c) Gary Kavanagh, then Deputy Director of the Bureau of Program Operations for HCFA, provided the following testimony in response to questioning from Congressional Dingle:

> Mr. Dingle. So you have got a whole package. You have told us that you are addressing the question of drug costs, pharmaceutical. I think that is splendid. But that is only a minute portion or at least a small portion of the overall costs of services of delivery to the patient, isn't this right?
>
> Mr. Kavanagh: That is correct, but the Medicare program does not pay for many of the services that were discussed earlier for home infusion therapy. We do not pay physicians for their services unless there is an office visit, or whatever, involved.
>
> We do not pay, unless it is a home health agency or a hospice, for a nurse to come in and provide home infusion therapy, because we do not have statutory basis to do so-the home infusion benefit is not a separate benefit under the Medicare program.

(*Id.* at 247.)

> * * *
>
> Mr. Dingle: . . . This leaves me with the regrettable conclusion that HCFA and HHS don't really have a clear pattern of payments for these kinds of services which work . . . . I sent that-and I want you to understand, this is what we call oversight here-that we have a system that is moving somewhat more slowly than the times, and that the services which are being given are being billed in ways that don't necessarily compensate anybody fairly, don't look to the interests of the taxpayers, don't look to the interest even of the beneficiaries. And the result is that the whole system seems to need some very substantial review.

(*Id.* at 248.)

(d) Miles Gilman, CEO for HealthInfusion, Inc., a home infusion provider, testified regarding the inadequacies of Medicare's payment structure for home infusion therapy. He testified:

> All of the elements of care are included in the price of the drug, ranging from nursing care to the overhead attributable to coordinating the care provided to the patient.
>
> I can assure you that providers do not want to do business in this fashion. However, as the reimbursement system is structured for infusion therapy today, providers often will not be able to cover the costs of their services if they do not include those costs in the price of the drugs and supplies.
>
> * * *
>
> Although it is commonly understood that it is the nursing and pharmaceutical services that enable infusion therapy to be provided in a home at all, Medicare's current coverage criteria still do not acknowledge that those services have any role in home infusion therapy.

(*Id.* at 172-173.)

107. In 2002, the National Alliance for Infusion Therapy/National Home Infusion Association sent a written statement to Congress. (Ex. 121 (Abbott Ex. 18).) That statement included the following comments:

- "Providers and suppliers of infusion drug therapies in the home setting are not paid separately by Medicare for the critical services and practice expenses described above. Medicare does not have a separate benefit for infusion therapy, but instead, infusion drugs provided in the home setting are covered exclusively under Medicare's benefit for durable medical equipment. The only items that are explicitly covered and reimbursed under this limited benefit are the drugs, equipment and supplies. Unlike other health care professionals who administer infusion and injectable drugs currently covered under Medicare Part B, providers and suppliers of home infusion drug therapies do not have a mechanism under Medicare that provides them with reimbursement for the services and facilities necessary to provide these therapies."

- "This is an extremely important point for policymakers to consider as they seek to reform outpatient drug reimbursement. Since the Medicare program does not explicitly reimburse pharmacists for their practice expenses and professional services (including such home infusion services as compounding), pharmacists currently are "paid" for these costs and functions primarily through reimbursement drugs. Similarly, Medicare does not explicitly pay for nursing services provided by infusion therapy providers. A nurse performs many functions, including patient screening and assessment, patient training regarding administration of the pharmaceuticals and general monitoring of the patient's

> health status. To the extent that Medicare reimburses for such services, it is largely through the drug payment. As explained in greater detail below, reductions in drug payments must be accompanied by a contemporaneous re-allocation of payment for these necessary professional services. If drug payments are reduced drastically without such a re-allocation, Medicare beneficiaries will not be able to receive home infusion drug therapy because the costs of therapy will exceed by a large margin the available reimbursement for the therapy.
>
> * * *

- "For the reasons stated above, at the present time the drug payments for infusion therapy subsidize other functions that the Medicare payment methodologies do not reflect appropriately. The costs of these services and functions far outweigh the costs of the drug product, but these costs are clearly lower than the charges that would be incurred if the patient received treatment in an alternate setting. For home infusion drug therapy, the drug payment is the only available payment mechanism for the services that are essential to providing good quality care. The long-standing use of AWP to determine reimbursement has masked the failure of Medicare and Medicaid payment policies to define and account for the service component."

- "If changes to the methodology used to calculate drug reimbursement result in substantially reduced drug payments, without corresponding changes to ensure adequate reimbursement for the service component of providing infusion therapies, the end result will virtually guarantee an inability of providers to continue to provide these services. Without the availability of home infusion services, Medicare beneficiaries will be treated in more costly settings."

108. When asked for his understanding of why Congress retained the 95% of AWP methodology for vaccines and infusion drugs administered through durable medical equipment, Tom Scully, the Former CMS Administrator, testified:

> Q. And so at least for the drugs that are subject to this carveout in the home infusion setting, Congress has kept the reimbursement of those drugs at 95 percent of AWP as of --
>
> A. As of October 2003.
>
> Q. That's correct, isn't it?
>
> A. I guess it is. That's what the statute says. Another piece of sausage. I have just forgotten that we did that, to be honest with you, which I assume is why they don't have a dispensing fee for anything but respiratory drugs, because they didn't do that for respiratory drugs.

> Q. So it would appear that Congress, at least for these drugs and in that setting of home infusion, has determined to continue to subsidize the provision of the services by overpaying for the drugs, correct?
>
> MR. GOBENA: Object to the form. The legislation speaks for itself.
>
> MR. BREEN: Objection to the form.
>
> BY MR. DALY:
>
> Q. You can go ahead.
>
> A. Yes. I was surprised to see this. I forgot we did it. It was certainly never discussed by members. I'm sure the staff -- staff person who wrote it works with me at Alston & Bird, so I'll go back and ask him, but I'm sure that it's probably, they froze it to freeze it, and some level of cross-subsidy apparently. I'm not sure what the congressional intent there was, but I think it was Senator Grassley's staff that did that provision. So I had totally forgotten we did it. That it was in the bill. It wasn't something that was widely discussed at all.

(5/15/07 Scully Dep. 365:22-367:10, Ex. 68.)

109. On or around May 18, 2000 CMS Deputy Administrator Michael M. Hash drafted a memorandum to HHS Deputy Secretary Kevin Thurm regarding the DOJ AWPs. (Ex. 122 (HHC902-214-44.) The memorandum includes the following statements:

- "**Issue** We have been considering options for using the alternative average wholesale price (AWP) data provided by DOJ. While we believe that Medicare overpays for the drugs identified by DOJ we also must assure continued beneficiary access to these drugs Per your request we have met with physician and provider groups who furnish Medicare beneficiaries with the drugs on the DOJ list and conducted some impact analyses dilemma arises from the fact that delivery systems have developed around overpriced drugs Reductions in the reimbursement particularly in the magnitude contemplated by the DOJ could disrupt these systems of care. . . ."

- **Background** We recently met with organizations representing oncologists urologists the end-stage renal disease community hemophilia suppliers and suppliers of asthma equipment/drugs and home infusion therapy to discuss their concerns about our use of the DOJ alternative AWP data as basis for determining

> Medicare's outpatient drug allowances which are currently based on 95 percent of the AWP. . . .
>
> - These organizations argued that 1) a high profit margin on drugs is necessary to cross-subsidize costs that are underfunded, such as drug administration; 2) beneficiaries would have limited access, as they would possibly have to receive care in more costly less convenient settings; 3) quality of care could deteriorate since, the DOJ list does not cover all drugs and there would be substitution of potentially less effective drugs for which the inflated payment could still be obtained; 4) there is insufficient time and information to successfully implement the change, and the policy was announced without adequate comment from stakeholders -- transition period was seen as critical; and 5) and in exploring an option to pay for drugs based on acquisition costs there was view that acquisition costs should include an adjustment for spillage and additional paperwork and there should not be national limit such as the median actual acquisition costs in Medicare in prior year."
>
> - "While some of the arguments raised by these organizations appear to have merit, we do not think it is clear in every case made that Medicare payment is inadequate to cover drug administration costs, and that access and quality of care would suffer if we implement the DOJ data. Also, we can not lose sight of the fact that lower drug payments would result in lower cost-sharing and Part premiums for beneficiaries. We continue to believe that Medicare payment for outpatient drugs is excessive, and that our payment systems should be calibrated to pay correctly for covered drugs and for delivery of those drugs."

(*Id.*) The Government withheld this document under the deliberative process privilege until the Court ordered its production on November 5, 2008 after an *in camera* review.

110. On March 6, 2009, Dr. Elvin Montanez, a pharmacist with extensive first-hand experience in the home drug infusion industry, submitted an expert report on behalf of Abbott in this case. Dr. Montanez's report described the home infusion industry, how services and the specific costs associated with home infusion therapy. (Ex. 92, Expert Report of Dr. Elvin Montanez.) Dr. Montanez's report further describes the ineffectiveness of the Medicare reimbursement system with respect to the home infusion industry from 1991-2001, as there was no direct reimbursement mechanism to account for the service component variables or quantities of medical supplies required. (*Id.* at 24.) Dr. Montanez also states that most state Medicaid programs did not provide sufficient compensation for the cost necessary to provide home

infusion. (*Id.*) As such, Dr. Montanez states that it was well-recognized in the industry that from "1991-2001, home infusion providers relied upon the differential between the actual cost of the medication and the AWP to subsidize the cost of infusion drug therapy that Medicare and Medicaid payment methodologies did not recognize." (*Id.* at 24-25.) Dr. Montanez provides that "this differential was the only payment mechanism available from Medicare and many Medicaid programs to compensate for the higher costs" associated with the costs associated with administering home infusion treatments. (*Id.* at 25.) Finally, Dr. Montanez opines that the differential between the drug cost and the published AWP "was accepted as the method that CMS and state programs would keep the provider whole while providing access to care." (*Id.*)

111. Mr. John Carmody, former President of OptionCare of Western Illinois and later Cottage Home Options, a company which provided home health services, signed a sworn declaration whereby he provided information regarding the home infusion industry and Medicaid reimbursement. Mr. Carmody stated that he recalls specific conversations during the mid-1990s that he had with Ron Gottrich, who then worked for the Illinois Medicaid program (Ex. 90, Carmody Declaration at 1.) During those conversations, Mr. Carmody explained to Mr. Gottrich that there were considerably higher costs associated with preparing and delivering compounded prescriptions, including Vancomycin and associated diluents, in the homecare setting. (*Id.* at 1-2.) Mr. Carmody wrote that Mr. Gottrich understood and acknowledged the higher costs associated with administering home infusion therapy and knew "that the dispensing fee paid by Illinois Medicaid (which he acknowledged was designed for retail pill prescriptions) did not come close to covering the costs to dispense home infusion drug therapies." (*Id.* at 2.) Mr. Carmody recalls "Mr. Gottrich indicating that the 'split' between AWP and providers' acquisition costs on the drugs served to partially compensate home infusion providers for the

extra costs associated with home infusion therapy." (*Id.*) Mr. Carmody stated that "[i]t was well-understood and agreed that the split between AWP and actual acquisition cost was providing the payment necessary to cover the extra costs of home infusion drug therapy." (*Id.*) Mr. Carmody stated that "[t]his was how Illinois Medicaid paid home infusion providers for dispensing home infusion drug therapies to Illinois Medicaid beneficiaries until early 2000," when the Illinois Department of Public Aid "drastically reduced reimbursement for the 'drug component' of several intravenous therapies. (*Id.* at 2-3.) In response to this, Mr. Carmody sent a letter to three Illinois legislators to express his concern over the change in the reimbursement policy. (*Id.* at 3.) Mr. Carmody indicated that "[s]ubsequent to the change in policy, I observed that Illinois Medicaid beneficiaries faced challenges obtaining access to home infusion drug therapies" and that he was "aware of several home infusion companies that quit providing services to Medicaid patients because doing so was no longer fiscally feasible." (*Id.*)

112. On June 12, 2000, Mr. Carmody wrote a letter to Congressman Lane Evans, Senator Carl Hawkinson, and Representative David Hultgren. The letter included the following statements:

- "A significant issue regarding governmental reimbursement for our [home infusion]services has suddenly occurred . . . . On May 1st of this year the Illinois Department of Public Aid drastically reduced reimbursement for the 'drug component' of IV medication based upon an investigation which was promulgated by the Federal Department of Justice."
- "Some years ago when the State of Illinois developed its current reimbursement mechanism, I had many discussions with the then pharmacy coordinator, Ron Gottrich concerning the mechanism for reimbursing IV medications. It is well understood that the dispensing fee in NO WAY is able to compensate the pharmacy organization for the costs of preparing and delivering compounded I.V. solutions, HOWEVER, it was further understood that IV pharmacies were and are able to purchase pharmaceuticals at well below AWP pricing thus partially compensating them for the costs from the drug component." (emphasis in original)

- "[T]here are significant costs associated with the preparation and delivery of sterile intravenous products for patient home use that are NOT seen in the standard 'pour and count' practice i.e. traditional pharmacy practice. Such costs include accreditation by JCAHO (Joint Commission on Accreditation of Homecare Organizations), which as an aside our last accreditation was $27,000; significantly more pharmacist time which must be spent on professional activities, delivery costs and certainly far greater time spent in compounding activities – illustratively it takes less than a minute to count pills and label a vial while it may take hours to compound complex sterile IV products." (emphasis in original)

- "[M]y pharmacy, which is one of the larger in the area is unable to purchase anything under the revised pricing which has been issued. If we therefore assume that I am to cover my costs under the dispensing fee, which both sides agree is inadequate to do so, it should leave me with no rational business alternative than to reduce my services to Medicaid and Medicare patients."

(Ex. 123, 6/12/00 Letter from J. Carmody) (Ex. A to Carmody Declaration.)

113. Mr. Ron Gottrich, Consultant Pharmacist for the Illinois Department of Public Aid (IDPA) from 1980 to 2004, signed a sworn declaration whereby he provided information regarding Illinois's reimbursement policies from the time of his employment as well as information relating to the provision and reimbursement for home infusion services by Illinois Medicaid. (Ex. 91, Gottrich Affidavit).

- Mr. Gottrich "was very familiar with the policies underlying Illinois's reimbursement to providers for dispensing prescription drugs to Illinois citizens eligible to receive Medicaid assistance." (*Id.* at 1.)

- "During the entirety of my time at [Illinois Department of Public Health], I was aware that the Average Wholesale Prices, or 'AWPs,' published in the drug compendia, such as *Red Book* and *Blue Book/First Databank*, were list prices not reflective of the actual prices – net of discounts, rebates, and chargebacks – paid by pharmacies in the marketplace." (*Id.*)

- "In particular, I was aware that the differences between AWPs published in the compendia and the actual prices paid in the marketplace were significantly greater for generic drugs. I was also aware that the differences between AWPs published in the compendia and the actual prices paid in the marketplace could be substantial for intravenous solutions (such as sodium chloride and dextrose) and injectable drugs commonly infused or injected into patients." (*Id.* at 1-2.)

- "It was commonly discussed amongst those who administered Illinois Medicaid pharmacy benefit that the dispensing fees paid by Illinois Medicaid were not

sufficient to cover pharmacies' cost to dispense Medicaid to Medicaid participants, much less provide a profit." (*Id.* at 2.)

- "It was also commonly discussed amongst those who administered Illinois Medicaid pharmacy benefit that Illinois Medicaid's reimbursement formula for ingredient cost provided a margin relative to the cost of the drug, and that this margin service to both offset the inadequacy of the dispensing fee and compensate for the fact that Illinois Medicaid did not reimburse drug claims in a timely manner." (*Id.*)

- Mr. Gottrich "recall[s] having conversations with Mr. Carmody" and "[t]he discussions referenced by Mr. Carmody in his [June 12, 2000] letter are consistent with my recollection of numerous conversations with pharmacists over the years where it was recognized and understood that the margin paid on ingredient cost served to offset the acknowledged inadequacy of Illinois Medicaid's dispensing fee and the delay in receiving payment from Illinois Medicaid. (*Id.* at 3.)

- Mr. Gottrich stated that "I would agree that pharmacies dispensing IV medications have higher costs that are not seen in the traditional retail pharmacy practice." *Id.*)

- "[I]t was also well understood by pharmacists and Medicaid officials with whom I spoke that the difference between AWPs published in the compendia and the actual prices paid in the marketplace could be substantial for intravenous solutions and other injectable and infusion drugs commonly used by IV pharmacies." (*Id.* at 3-4.)

2. Federal Upper Limits

114. Pursuant to the Omnibus Reconciliation Act of 1990, "HCFA shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically equivalent and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit." (Ex. 102 (Abbott Ex. 463).)

115. Sue Gaston worked as a Health Insurance Specialist at HCFA from 1991 to 2003, reporting to Larry Reed. During this time, Gaston's responsibilities included overseeing policy-related issues for the Medicaid drug rebate program and working on Medicaid pharmacy reimbursement matters, such as drug coverage, payment issues, and reviewing state plan

amendments. (1/24/08 Gaston Dep. 40:7-42:8, Ex. 26.) Gaston was also responsible for setting Federal Upper Limits ("FULs"). (*Id.* at 45:2-5.)

116. Between 1991 and 2003, Gaston, Peter Rodler, and Cindy Bergin were the personnel involved in setting FULs. (1/24/08 Gaston Dep. 223:16-224:19, Ex. 26.) Rodler trained Gaston to set FULs in 1991. (3/19/08 Gaston Dep. 404:1-6, Ex. 27.) Rodler left in the mid-1990s, and Gaston was solely responsible for setting FULs until Bergin arrived in 1999. (*Id.* at 404:7-406:2.) After 2003, Gail Sexton became involved in setting FULs. (1/24/08 Gaston Dep. 224:4-8, Ex. 26.)

117. Gaston was aware that there was a large difference between acquisition costs and AWPs for certain injectable and infusion drugs based on the Ven-A-Care litigation and presentation in the mid-1990s. (3/19/08 Gaston Dep. 319:13-320:10, Ex. 27.) Gaston testified that, although she was aware of the difference, CMS "did not set FUL prices on those types of drugs. . . it would be a matter of changing the criteria. And that wouldn't be strictly my place to do that." (*Id.* at 327:3-328:19.)

118. Gaston testified that CMS "didn't set federal upper limit prices on injectable drugs or infusion drugs. [They] set them on drugs that were the most commonly used such as tablets, capsules, creams." (3/19/08 Gaston Dep. 320:17-321:6, Ex. 27.) Gaston is not aware of any statute or regulation that prohibited FULs for injectables or infusion drugs. CMS's internal criteria that FULs would apply to "drugs that were considered outpatient drugs, generally dispensed at the pharmacy level" was established before Gaston started working in the federal upper limit program. (*Id.* at 321:12-322:3.)

119. With the exception of 00074-6138-02, 00074-6138-03, 00074-6138-22, 00074-7138-09, 00074-7924-09, and 00074-7972-05, each of the complaint NDCs met the criteria for

the establishment of a FUL. (Ex. 94 at 32 n.51 (Expert Report of Steven J. Young) ("The majority of the NDCs in this matter met the requirements to have a FUL calculated, but the CMS did not do so.").)

120. CMS uses a computerized system to collect initial data for determining FULs. (1/24/08 Gaston Dep. 235:2-237:9, Ex. 26.) The system pulls data from the Orange Book for drugs that meet the criteria for FULs. (*Id.* at 237:10-238:12.) Ms. Gaston testified that CMS specifically set up the computer program to identify and exclude injectable drugs. (*Id.* at 248:13-17.) She did not know why CMS did this. (*Id.* at 248:21-249:12.)

121. Ven-A-Care's Zachary Bentley testified that he had conversations with Gaston wherein he inquired why CMS did not establish FULs for infusion and injectable drugs. Mr. Bentley testified:

> Q. Tell me about your conversations with Larry Reed and Sue Gaston.
>
> A. Sue Gaston, at this time, I don't know what she does now, she was in charge of determining the federal upper limit for Medicaid drugs, and Larry Reed was, I believe, her boss.
>
> Q. When did you speak to Ms. Gaston and Mr. Reed?
>
> A. I spoke to Sue Gaston several times. I don't remember the dates or times. I think Larry Reed I may have had one or two conversations with prior to this meeting.
>
> Q. What was the occasion for your speaking with Ms. Gaston and Mr. Reed?
>
> A. It would have had to have done with the Medicaid payment for prescription drugs.
>
> Q. Approximately how long before September of 1995 did you first speak to Ms. Gaston or Mr. Reed?
>
> A. I don't remember.
>
> Q. Was it more than a year before this time?

A. With Sue Gaston, I'm fairly confident that it was probably several years prior.

Q. How did you come to speak to Ms. Gaston at HCFA?

A. I got her name and telephone number from somebody. I don't know how, but certainly I got her name and spoke to her.

Q. Why did you want to speak to Ms. Gaston?

A. Like I say, it would have -- it would have had to do with issues regarding Medicaid prices or reimbursement for prescription drugs.

Q. What was your purpose for calling Ms. Gaston?

A. I don't remember exactly, whether I was seeking information, or whether I was wishing to give her information. I was probably asking her for information.

Q. What type of information were you asking from Ms. Gaston?

A. I think one of the questions that I was curious about was how she went about formulating the, or the methodology used in establishing the federal upper limit or FUL.

Q. Now, there were no FULs established for infusion drugs as I recall. Correct?

A. That's correct.

Q. Did you ask Ms. Gaston about that?

A. Yes. I can't remember her answer. And I also asked her who determines what drugs go on the federal upper limit, because to my knowledge I couldn't find any rules or regulations that articulated exactly how a drug got chosen to be on the federal upper limit. So I was curious as to what that process was. To the best of my knowledge, I think she said it was within her discretion.

Q. Did Ms. Gaston give any indication as to why she was exercising her discretion not to establish a federal upper limit for infusion drugs?

A. No.

Q. Do you have under -- did you have any understanding as this time about why it was that HCFA had not established a federal upper limit for infusion drugs?

A. No, I don't -- I don't know why they didn't.

(3/5/08 Bentley Dep. 322:17-325:16, Ex 8.)

122. Jerry Wells, the former Pharmacy Program Director in Florida, also testified about conversations with CMS officials regarding the lack of FULs on infusion and injectable drugs. Mr. Wells testified:

> Q. Do you recall any specific conversations that related to whether or not injectable or infusion drugs, including those listed on Pages 10 and 11 of Exhibit 1002, would be included within the federal upper limit program?
>
> A. No. As I said, I think they excluded them. It was not their intent to put federal upper limit prices on those drugs.
>
> Q. Do you know why it was that HCFA -- strike that. Were you ever told by anyone at HCFA why it was that HCFA intended to exclude injection and infusion drugs from the federal upper limit program?
>
> MS. ST. PETE-GRIFFITH: Object to form.
>
> THE WITNESS: I don't recall.
>
> BY MR. COOK:
>
> Q. From your conversations with Larry Reid and others at HCFA, were you able to infer why it was that the federal government excluded injection and infusion drugs from the federal upper limit program?
>
> MS. WALLACE: Objection.
>
> MS. ST. PETE-GRIFFITH: Objection.
>
> THE WITNESS: I don't think that I was ever satisfied or got a satisfactory answer for my purposes or that issue, but I just don't recall. That's many years ago.
>
> BY MR. COOK:
>
> Q. Did you seek a satisfactory answer?
>
> MS. ST. PETE-GRIFFITH: Object to the form.

> THE WITNESS: I think we had some discussions about it because I felt like they should, and they had some reasons that, as I said, I don't think I was ever satisfied with, but I don't even recall what their reasons were.
>
> * * *
>
> Q. You indicated that you never got a satisfactory answer from HCFA. Did you ever get any answer from someone at HCFA as to why the federal upper limit program was not expanded to include injection and infusion products?
>
> MS. WALLACE: Objection.
>
> MS. ST. PETE-GRIFFITH: Object to the form.
>
> THE WITNESS: I may have. These were philosophical discussions, and we had lots of differences of opinion about what ought to and ought not to be done in managing the prescription drug program. I don't recall the answer. Obviously, it didn't stick in my mind or I'd tell you what it was.
>
> BY MR. COOK:
>
> Q. And to be clear, the -- your inability to testify about why it was that HCFA told you is a function of the passage of time, correct?
>
> MS. ST. PETE-GRIFFITH: Object to the form.
>
> MS. WALLACE: Objection.
>
> THE WITNESS: Yeah, I think the function of the passage of time, and it wasn't -- apparently, wasn't satisfactory enough to stick.

(12/15/08 Wells Dep. 48:11-50:4, 55:11-56:3, Ex. 85.)

3. State Reimbursement Level

123. The Centers for Medicare & Medicaid Services has published a summary chart entitled "Medicaid Prescription Reimbursement Information by State – Quarter Ending June 2009," at http://www.cms.hhs.gov/Reimbursement/Downloads/reimbursementchart2q2009.pdf. The summary chart indicates that nearly every state Medicaid program sets its ingredient cost

reimbursement level by reference to AWP, either in whole or part, as of the quarter ending June 2009. (Ex. 103.)

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Carol P. Geisler, an attorney, hereby certify that I caused a true and correct copy of the foregoing to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 28th day of August, 2009.

/s/ Carol P. Geisler
Carol P. Geisler